Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A. Guzman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 1867	DATE	3/21/2002
CASE TITLE	ABBOTT LABORATORIES vs. BAXTER PHARMACEUTICAL PRODUCTS		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] It is hereby ordered that the objections to Magistrate Judge Ashman's order of 6/27/01 are overruled and Magistrate Judge Ashman's Report and Recommendation is adopted in full. Enter memorandum Opinion and Order.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.		MAR 22 2002	
	Notices mailed by judge's staff.		date docketed	
	Notified counsel by telephone.			
✓	Docketing to mail notices.	U.S. DISTRICT COURT CLERK 02 MAR 21 PM 4:27 FILED-ED 10	docketing deputy initials	67
	Mail AO 450 form.		date mailed notice	
	Copy to judge/magistrate judge.			
CG	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois corporation, and CENTRAL GLASS COMPANY LTD. a Japanese corporation,	)	
Plaintiffs,	)	**Judge Ronald A. Guzman**
	)	**No. 01 C 1867**
v.	)	
BAXTER PHARMACEUTICAL PRODUCTS, INC., a Delaware corporation, and BAXTER HEALTHCARE, CORP. A Delaware corporation,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Before this court are plaintiffs Abbott Laboratories and Central Glass Company Ltd. objections to Magistrate Judge Ashman's order of June 27, 2001. For the reasons set forth below these objections are overruled and Magistrate Judge Ashman's Report and Recommendation is adopted in full.

BACKGROUND FACTS

Plaintiffs Abbott Laboratories and Central Glass Company Ltd. ("Abbott") have filed a complaint alleging infringement of U.S. Patent No. 5,990,176 ("'176") by defendants Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corp. ("Baxter"). Defendant's contend that their amended Abbreviated New Drug Application ("ANDA"), filed under the Hatch-Waxman Act for a generic sevoflurane product, does not infringe Abbott's patent either literally or under

67

the doctrine of equivalents. On February 26, 2001 this court referred all discovery supervision and all pretrial motions to Magistrate Judge Ashman. On April 13, 2001 Baxter moved for summary judgment arguing non-infringement of the '176 patent by its generic sevoflurane. Abbot claimed that it was unable to respond fully to Baxter's motion for summary judgment and, why, under Fed. R. Civ. 56(f), the court should refuse summary judgment until Abbott had an opportunity to conduct more discovery. Magistrate Judge Ashman ordered Abbott to file a FRCP 56(f) statement identifying the specific discovery that was needed. Abbott did so. Magistrate Ashman then ordered Baxter to answer interrogatories and produce a 30(b)(6) witness and refused to order any other discovery. Abbott has filed objections to Magistrate Judge Ashman's order.

DISCUSSION

Before addressing Abbott's objections, the court observes that a district court's review of any discovery-related decision by a magistrate judge is governed by Fed. R. Civ. P. 72(a). The district court will not modify or set aside a magistrate's ruling unless the ruling is contrary to law or the factual findings are clearly erroneous. Fed. R. Civ. P. 72(a). A finding is clearly erroneous when, after considering the entire record, the reviewing court has been definitely and firmly convinced that a mistake has been committed. *Hughes v. United Van Lines, Inc.,* 829 F. 2d 1407, 1416 (7th Cir. 1987), *cert. denied* 485 U.S. 913 (1988). Therefore, the reviewing court will not reject the magistrate's findings of fact simply because it would have decided the case differently.

Abbott argues that Magistrate Judge Ashman's order is clearly erroneous because a *Markman* hearing with experts is required to properly construe the claims. Abbott claims that in order to determine infringement, both literally and under the doctrine of equivalents, an analysis

of the nature, composition, and function of Baxter's accused products must be made. The key issue is whether the accused Baxter product has "a Lewis acid inhibitor in an amount effective to prevent degradation" or an equivalent thereof. Baxter's position is that Abbott's claims, as defined by its patent, only cover a product with a water content of at least 150 parts per million, the "effective amount." To answer this question, Abbott contends, information relating to the composition of Baxter's product, the water level, how the water level is determined, when the water level is tested, and the methodology used to determine the water level is required.

We find the objections insufficient under the standard set forth in Rule 72(a). Baxter's position on summary judgment is very limited. Baxter contends that their amended Abbreviated New Drug Application (ANDA), filed under the Hatch-Waxman Act for the generic sevoflurane product, does not infringe Abbott's patent, U.S. Patent No. 5,990,176, either literally or under the doctrine of equivalents. Baxter is taking the position on summary judgment that you should only look to two documents–Baxter's ANDA filing and Abbott's patent. When seeking approval for a generic drug filing an ANDA is an alternative means of obtaining FDA approval. The Hatch-Waxman Amendments to the Food, Drug & Cosmetics Act state that a party seeking approval of a generic drug may file an ANDA with the FDA and rely upon the findings of safety and effectiveness set forth in the pioneer drug owner's New Drug Application. 21 U.S.C. § 355(j) (1997). In addition to filing the ANDA, the applicant must certify either that: (1) no patent for the pioneer drug has been filed; (2) the pioneer drug patent has expired; (3) the pioneer drug patent will expire on a certain date; or (4) the pioneer drug patent is invalid or will not be infringed by the proposed generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii). If the applicant files a so-called "Paragraph IV Certification," the owner of the pioneer drug has forty-five days in

which to file a patent infringement suit against the applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within forty-five days, the FDA approval proceeds. *Id.*

Baxter cites to *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F. 3d 1241 (Fed. Cir. 2000), and *Abbott Laboratories v. Torpharm, Inc.*, No. 97 C. 7517, 2001 WL 315343 (N.D. Ill. Mar 30, 2001). Both these cases both suggest that if an ANDA directly addresses the issue of infringement then the court simply compares the ANDA with the patent. *Bayer AG v. Elan Pharmaceutical Research Co.*, 212 F. 3d 1241 (Fed. Cir. 2000) dealt with a lawsuit similar to ours in that Bayer, the manufacturer and holder of a patent for high blood pressure medicine brought an infringement action against another manufacturer who had filed an ANDA in order to produce generic version of patented drug. The Court of Appeals affirmed the district court's finding of non-infringement specifically concluded the following:

> We see no error in the district court's grant of summary judgment of no literal infringement in favor Elan. Thirty-five U.S.C. § 271(e)(2)(A) provides that it shall be an act of infringement to submit an ANDA "if the purpose of such a submission is to obtain approval...to engage in the commercial manufacture, use, or sale of a drug...claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." The focus, under § 271(e)(2)(A), in on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Glaxo,* 110 F. 3d at 1569, 42 USPQ2d at 1263. '[T]his hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support." Therefore, it is proper for the court to consider the ANDA itself, materials submitted by the ANDA itself, materials submitted by the ANDA applicant in support to the ANDA, and any other relevant evidence submitted by the applicant or patent holder. *See id.* At 1570, 110 F. 3d 1562, 42 USPQ2d at 1263. However, if the ANDA "is to sell [a] well-defined compound, "then the "ultimate question of infringement is usually straightforward." *Id.* at 1569, 110 F. 3d 1562, 42 USPQ2d at 1263.

Bayer at 1248.

Obviously, *Bayer* is a source of support for Magistrate Judge Ashman's decision not to

order additional discovery and it cannot be concluded that his ruling is erroneous under the Fed. R. Civ. 72(a). Furthermore, much of the discovery that Abbott's seeks relates to the actual product that Baxter intends on making. Since it is the filing of an ANDA that allows a plaintiff to file an infringement suit, it is the ANDA that should be referenced not the proposed physical product or the manufacturing process of the potential product. Furthermore, it is the ANDA and the exhibits offered in support of the application that the FDA looks to in determining whether element 4 of the certification has been satisfied. *See* 21 U.S.C. § 355 (j)(2)(A)(vii). Because the meaning of a patent claim is fixed on the day the patent was issued by the PTO, Abbott does not need additional discovery from Baxter to construe Abbott's own claims.

CONCLUSION

For the reasons set forth above Abbott's objections are overruled and Magistrate Judge Ashman's order adopted in full.

So ordered.

Entered

Judge Ronald A. Guzman
United States Judge
3/21/02